Exhibit B

Report re Prolift

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This report contains a summary of my qualifications, education, training, and experience, a statement of my opinions that I have formed to date, the bases for those opinions, and the information I considered in forming my opinions. All of my opinions are based on my education, training, clinical experience, the pertinent medical literature, discussions with colleagues, and other materials I have reviewed. Materials that support my findings and opinions, including documents that I have reviewed, are identified either in this report or are listed in the attached reliance materials list.

All of the opinions I express in this report are held to a reasonable degree of medical and scientific certainty. If I receive additional information after signing this report but before trial, I may form additional or different opinions.

I. Background

a. Education, Training, and Experience

I attended the University of Florida in Gainesville, Florida, graduating with a Bachelor of Science degree in Chemistry with High Honors in 1976. I attended medical school at George Washington University, graduating in 1982. I then did a surgical internship in 1982–1983 at the Portsmouth Naval Hospital in Portsmouth, Virginia. Following my internship, I did a urological residency at the Portsmouth Naval Hospital from 1984–1988. I served as Chief of Urology at Jacksonville Naval Hospital in 1990-91.

Prior to my residency, I served in Operation Urgent Fury in Grenada in October 1983 and as part of the Multinational Peacekeeping Force in Beirut, Lebanon in 1983–1984. After my residency, I served in Operation Desert Shield and Operation Desert Storm with the 1st Marine Division, stationed in Saudi Arabia and Kuwait in 1990–1991.

I am the President-Elect of the Medical Staff at Swedish/Edmonds Hospital in Edmonds, Washington. I also serve as the Chair of Swedish Hospital's Medical Quality Oversight Committee, Chair of the Credentials Committee, Treasurer of the Medical Staff for the Swedish Hospital System, and as a member of the Executive Committee at Swedish Hospital.

I became a Diplomate of the American Board of Urology in 1990 and was recertified in 2010. I am an active member of the American Urological Association, the Washington State Medical Association, the Northwest Urological Society, the Washington State Urology Society, the King County Medical Society, the American Association of Clinical Urologists, the Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction, and the International Continence Society.

My curriculum vitae is attached to this report.

b. Clinical Experience & Personal Experience with Stress Urinary Incontinence and Pelvic Organ Prolapse Treatments

I have a special focus in female pelvic medicine and surgery. Over the course of my career, I have performed various types of native tissue surgery and surgery utilizing mesh, including Ethicon's TVT and TVT-O, TVT-Abbrevo, and TVT-Secur mid-urethral slings, AMS Monarch, Uretex by Bard, Vesica In situ sling, Stamey cystourethropexy, MMK, and Burch procedures. I have also performed robotic sacrocolpopexies, as well as open abdominal sacrocolpopexies. I have also performed various types of native tissue surgeries and surgeries utilizing mesh—including the Prolift device—to treat pelvic organ prolapse.

c. Teaching & Training Experience Related to Stress Urinary Incontinence

I served as a faculty member at the Ethicon Endosurgical Institute, and as a National Preceptor for Gynecare products, conducting over 300 courses for advanced surgical training of physicians for conditions such as stress urinary incontinence and pelvic organ prolapse. I have lectured to pelvic floor surgeons throughout the United States, Canada, Europe, and China. I have performed research in the field of incontinence and bladder disorders, contributing to studies on the use of TVT abdominal guides, and the TVT world registry published in the Journal of Urology in 2011. I was also an investigator in an FDA trial of a pelvic nerve stimulator for the treatment of urge incontinence.

d. Litigation Consulting Work

During the previous four years, I have testified as an expert witness at trial or by deposition in the following case:

- Perry v. Ethicon, Inc., et al.—Bakersfield, CA
  - Deposition Testimony on 12/30/14
  - Trial Testimony on 02/17/15, 02/18/15, and 02/19/15

I am being compensated $500 per hour for my study and testimony in this case.

IV. Pelvic Organ Prolapse

a. Definition, Mechanism of Action, and Prevalence

Pelvic organ prolapse, overactive bladder, and urinary incontinence affect more women than diabetes, heart disease, or arthritis. The overall lifetime risk for undergoing surgery for pelvic organ prolapse is 11.1% or 1 in 9 women by the age of 80. The risk of surgery increases to 16% status post hysterectomy.

The proposed mechanism of action for the development of pelvic organ prolapse begins with damage to the levator ani muscles and nerves which decreases muscle tone and strength,

leading to muscular disuse atrophy causing descent and a widened levator hiatus. Increased intra-abdominal pressure is then unopposed, placing additional forces on the connective tissue, which stretches and tears over time. Pelvic organ prolapse is most common in the anterior compartment and then posterior compartment, with apical prolapse the least common as a site-specific defect.

b. Risk Factors for Stress Urinary Incontinence

Smoking: Women who smoke have a 2-3 times more likely incidence of urinary incontinence chronic obstructive pulmonary disease and increasing abdominal pressures causing pelvic organ prolapse.

Obesity: Increasing body mass index correlates to an increase in the symptoms of urinary incontinence and pelvic organ prolapse.

Menopause: Decreasing serum levels of estrogen are known to increase the incidence of both stress incontinence and decrease the integrity of the pubocervical fascia of the vagina by decreasing vascularity and thickness of the tissues. Postmenopausal decreased estrogen levels lead to urogenital atrophy with the increased risk of infections of the urinary tract and changing of the vaginal pH.

Pregnancy and Childbirth: Damage sustained to the muscles and nerves of the pelvic floor significantly increase the risk of both stress and urge incontinence and pelvic organ prolapse. There is an 11-fold increased risk of pelvic organ prolapse with three or more vaginal deliveries compared to nulliparous women. The weight of the infant contributes to prolapse with an increase of 10% per pound weight of the infant.

Race: Increasing incidence of prolapse occurs from African-American < Asian<Caucasian<Hispanic. Hispanic women have the highest risk of pelvic organ prolapse

Age: Pelvic organ prolapse levels increase with each decade for women between the ages of 20 and 59 years and the incidence of prolapse requiring surgery also has a dramatic increase with each successive decade.

Congenital factors: Women with prolapse having an abundance of the weak or type III collagen in the pubocervical fascia with a higher degree of joint hypermobility with associated collagen vascular disorders also increase the incidence and severity of prolapse.

Hysterectomy: The lifetime risk of prolapse post-hysterectomy is 16% with no specific technique increasing risk. The incidence of women developing severe prolapse after hysterectomy is to 3.6 birth 1000 women years and if the hysterectomy was performed with initial complaints of prolapse or rate is as high as 15 per 1000 women years.

Stress Urinary Incontinence: 62% of women with prolapse also report stress incontinence, and 63% of women with stress incontinence have associated prolapse. 30% of women will undergo repeat surgery for recurrent prolapse over their lifetime.

V. Treatment Options for Pelvic Organ Prolapse

a. Nonsurgical Options for Treatment of Pelvic Organ Prolapse

Conservative management of pelvic organ prolapse is the avoidance of pelvic and abdominal straining in the form of heavy lifting or squatting. Patients can also be treated with physical therapy using biofeedback, Kegel exercises, estrogen vaginal supplementation, and pessaries.

b. Surgical Options for Treatment of Pelvic Organ Prolapse

Surgical corrections of pelvic organ prolapse have many different approaches—from either vaginal or retropubic—and involve open incisions or laparoscopic techniques. For relatively simple cystocele and rectocele repair, native tissue plication with absorbable sutures can be provided, but has a 30-50% 5-year failure rate based on multiple studies. Sacrospinous ligament fixation and uterosacral ligament repairs have higher rates of success, but also higher rates of complications including chronic pelvic pain, dyspareunia, urinary retention, and injury to adjacent organs such as the bladder, rectum, and vessels. Retropubic abdominal sacrocolpopexy performed either open or laparoscopically is also an option. It has the highest rate of success but also a significant rate of complications.

Due to the high rate of failure using native tissue plication and suture fixation, biologic and synthetic materials have been incorporated into repairs for over 30 years. Cadaveric fascia, autologous fascia, or synthetic meshes have been incorporated to augment the repair in an attempt to increase the anatomic long-term success. The augmented repairs have the same potential complications as native tissue plications, with additional possible complications of mesh exposure, extrusion, or perforation of adjacent organs. The rate of vaginal mesh exposure varies from 3% to 34% in various studies, and with small areas of exposure topical estrogen and time may be all that is required for treatment. For larger areas of exposure or pain, local excision can be performed using either local anesthetic or general anesthesia. Mesh excision can be performed in the office setting, or an outpatient surgery center, as well as hospitals.

Maher and colleagues analyzed 56 randomized controlled trials evaluating 5,954 women with the objective of determining "the effects of the many different surgeries used in the management of pelvic organ prolapse." They studied 21 trials that compared various surgical procedures for treating cystocele and found that traditional anterior prolapse repair was associated with more anterior compartment prolapse than any polypropylene mesh repair. They found that patients were more aware of their prolapse after anterior native tissue repairs than were patients receiving a polypropylene mesh repair.[1] Weber and colleagues, in 2001, conducted a randomized controlled trial studying three surgical techniques for anterior colporrhaphy and found that only 30% of the patients in the standard anterior colporrhaphy

[1] Maher C, et al., Surgical management of pelvic organ prolapse in women, Cochrane Review 2013.

group had satisfactory or optimal anatomic results, compared to 42% in the standard plus mesh group and 46% in the unilateral anterior colporrhaphy group.[2]

Barber and colleagues showed that the success rates of sacrospinous ligament fixation and uterosacral ligament fixation were nearly equal at 60.5% and 59.2%, respectively.[3] Failure of native tissue repairs is common and can occur when sutures break, pull through the tissue, or are prematurely absorbed.

c. Pelvic Organ Prolapse's Economic Impact and Impact on Quality of Life

Pelvic organ prolapse can have significant adverse effects on the quality of women's lives. It can be painful, can negatively affect women's relationships, and it can cause patients to isolate themselves socially and be less active. Symptoms include a feeling that something is falling out of the vagina, a pulling sensation in the pelvic area, lower back pain, and a sensation of pressure of fullness from organs pressing against the vaginal walls. Patients with rectocele often have constipation as a result. The costs of pelvic organ prolapse surgery was calculated to be over a billion dollars in 1997.[4]

IV. Ethicon's Prolift Device

a. Historical Background of Surgical Use of Mesh

Polypropylene monofilament suture was introduced into surgery in 1958 by Usher, and has become the main material used in tissue repair. Polypropylene sutures have been used for over 55 years and are biologically compatible with human tissue. Polypropylene hernia mesh has been and continues to be the standard of care for the last thirty years for abdominal wall hernia repair. Polypropylene mesh has been used in open abdominal sacrocolpopexies since the 1960s. The advantage of mesh is augmentation and strength during the healing process with the incorporation of collagen fibers into the material to provide lasting support. I have been performing polypropylene mesh hernia repairs since the 1980s and have never had a patient develop an infection or rejection of the material.

Polypropylene meshes have been used in the vagina for almost 60 years. Surgeons have turned to synthetic materials to augment healing and reinforcement of poor-quality native fascia and collagen that has deteriorated both by years and trauma of parity. Due to the high failure rate of suture repairs for vaginal prolapse, mesh grafts have been developed to address the problem in the same manner as hernia repairs of the abdominal wall.

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[2] Weber AM, et al., Anterior colporrhaphy: A randomized trial of three surgical techniques. Am J Obstet Gynecol 2001 Dec. 185(6):1299–1306.

[3] Barber MD, et al., Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse – The OPTIMAL Randomized Trial. J Am Med Assoc 2014;311(10):1023–1034.

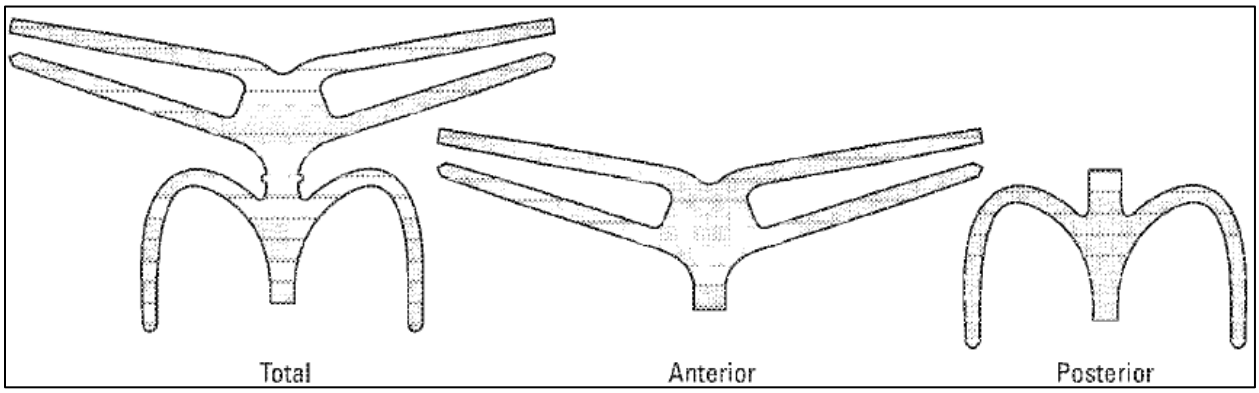
[4] Subak LL, Cost of pelvic organ prolapse surgery in the United States. Obstet Gynecol 2001 Oct;98(4):646–51.

b. The Development of the Prolift Device

Due to the high failure rates of native tissue repairs like colporrhaphies, the morbidity of open abdominal sacral colpopexy, the high failure rate and infection rates associated with biologic grafts, surgeons began using transvaginal mesh to treat pelvic organ prolapse. In 2000, a group of surgeons in France calling themselves the "TVM Group" started to study the use of non-absorbable synthetic mesh in urogenital prolapse repair, which was prompted by the 20–30% prolapse recurrence rates following traditional native tissue repairs. The TVM Group selected Prolene Soft mesh, as they found it to be the most appropriate mesh for the transvaginal approach of the surgical repair of prolapse. They noted that the Prolene Soft was "a carefully selected and tested synthetic material."[5]

In 2002, Gynemesh™ PS was introduced, and was "indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect." It was the first synthetic polypropylene mesh indicated for pelvic floor repair.

The Prolift device was introduced in March 2005. The Prolift device consists of pre-cut Gynemesh PS non-absorbable mesh implants and a set of instruments to facilitate mesh placement. It is implanted via a procedure "designed for and by surgeons."[6] The Prolift Total system consisted of an anterior and posterior implant had six straps—four for securing the anterior portion of the implant via a trans-obturator approach, and two straps for securing the posterior portion of the implant in the sacrospinous ligament via a trans-gluteal approach.



The Prolift system also included a Guide, Cannula, and Retrieval Device to facilitate passage and placement of the implant straps while protecting the surrounding tissue. It is inserted transvaginally, through a full-thickness vaginal incision. The mesh is placed through the arcus tendineus fascia pelvis (ATFP) or the sacrospinous ligament (SSL), and is placed tension-free.

The Gynemesh PS used in the device is a monofilament, knitted, macroporous, synthetic mesh. It is made of knitted filaments of extruded polypropylene identical in composition to that

[5] Berrocal J, et al., Conceptual advances in the surgical management of genital prolapse—The TVM technique emergence. J Gynecol Obstet Biol Reprod 2004;33:577–87.
[6] Prolift Surgeon's Resource Monograph.

used in Prolene polypropylene sutures that have been used in various surgical specialties for more than 50 years, and it includes blue Prolene monofilaments to produce contrast striping that makes the mesh more visible when implanted. The Prolift IFU notes that "[t]he mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh." The knitting process provides for elasticity in both directions—which "allows adaptation to various stresses encountered in the body." The IFU also notes:

> Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimal to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The mesh is a Type I mesh, per the biomaterial classification published by PK Amid in 1997, as it contains pores larger than 75 microns, "which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores." (Amid PK, Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997;1:15–21.) The pore size of Gynemesh PS is approximately 2,500 µm, and thus allows for excellent tissue integration and the passing of leukocytes and macrophages to clear any pathogens.

Prior to the commercial release of the Prolift device, Cosson and colleagues did a retrospective multi-center study of 687 patients treated with the Prolift mesh according to the protocol described by the TVM group surgeons.[7] The authors found intra-operative complications to be rare, occurring in only 1.32% of cases. They also found that short-term post-operative complications were uncommon, only occurring in 2.49% of patients. Only 1.32% of the patients experiencing post-operative complications required surgical treatment, and most of them were benign (1.75% hematomas and 0.29% perineal abscess). More serious complications like perineal cellulitis, vesico-vaginal or rectovaginal fistulas occurred in only 0.15% of cases each. Vaginal erosion or granuloma formation requiring surgical treatment occurred in 6.7% of patients. De novo stress incontinence occurred in 5.4% of the patients studied. The authors noted a 94.7% cure rate. Based on the study, the authors concluded that the technique was safe in the short-term, and that "Prolift mesh is obviously an interesting improvement in organ prolapse surgery."

c. The Safety and Efficacy of Gynemesh PS and the Prolift Device

Review of scientific reports of the use of Gynemesh and pelvic reconstructive surgery date back to 2001. De Tayrac described 36 patients undergoing cystocele repair using Gynemesh

[7] Cosson M, et al., Prolift Mesh (Gynecare) for Pelvic Organ Prolapse Surgical Treatment Using the TVM Group Technique: A Retrospective Study of 687 Patients. ICS 2005 Abs. 121.

with 13 month follow-up and 100% success with one mesh excision under local anesthesia for non-symptomatic exposure.[8]

Several studies demonstrate the versatility of Gynemesh PS, describing its use in various gynecologic procedures other than transvaginal procedures. Weiden described up to four-year follow-up of abdominal colposacropexy and hysterosacropexy using Gynemesh with bone anchoring and reported excellent anatomical results and low complication rates. This study is indicative of the many different uses to which the product can be put.[9] Agarwala describes in 2007 the use of Gynemesh for laparoscopic sacral colpopexy for recurrent prolapse of the apex or severe uterine prolapse. 74 patients were treated with Gynemesh. Subjective and objective cure was 97 and 100%, respectively. There were no cases of graft exposure or recurrence with a median follow-up of 24 months.[10]

Lucente in 2004 described 160 patients undergoing vaginal or abdominal/vaginal repair with a less than 10% exposure rate and success of 76% in reducing the prolapse to stage 0-1. The authors concluded that POP repair using GYNEMESH PS "is safe, with a low rate of significant mesh-related complications."[11] In 2006, Ali and colleagues described 108 patients undergoing anterior colporrhaphy with Gynemesh PS augmentation. They encountered no intra-operative complications, a 6.6% recurrence rate, and a 6.5% exposure rate.[12]

Collinet and colleagues described in 2006 the management of transvaginal mesh techniques for repair of pelvic prolapse using a vaginal approach and the use of Gynemesh. In the paper, it is described that the ideal mesh for pelvic reconstructive repair is monofilament polypropylene with large pores. The study was a continuous retrospective trial of more than two years, and was designed to identify the risk factors for exposure of mesh material and management strategies for postoperative complications. 277 patients undergoing surgery for pelvic prolapse using the TVM technique—using risk factors of body mass index, age, menopausal status, hormonal replacement therapy, previous surgical repair and hysterectomy—were included. Mesh exposure was less than 1% when the uterus was preserved. Management of mesh exposure involved local treatment combined with partial resection of the mesh if the local treatment proved inadequate. The local treatment was further enhanced with estrogen therapy.[13]

Deffieux described in 2006 management of 34 consecutive cases of vaginal mesh erosion following transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft. 68% underwent local therapy using an estrogen cream. In 22% of cases, the mesh erosion had completely

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[8] De Tayrac R, et al., Cystocele Repair with a Fixation-Free Prosthetic Polypropylene Mesh. Abs. 2001.
[9] Van der Weiden RMF, et al., Colposacropexy With Mesh or Collagen Implant and Titanium Bone Anchors Placed in Sacral Segments 3 and 4. J Pelvic Med & Surg 2003;9(1):9–14.
[10] Agarwala N, et al., Laparoscopic sacral colpopexy with Gynemesh as graft material—Experience and results. J Minimally Invasive Gynecol 2007;14:577–83.
[11] Lucente V, et al., A Clinical Assessment of GYNEMESH PS for the Repair of Pelvic Organ Prolapse. AUGS, SGS Oral Poster 55
[12] Ali S, et al., A Prospective Randomized Trial Using Gynemesh PS for the Repair of Anterior Vaginal Wall Prolapse. Int Urogynecol J 2006;17(Supp. 2):S171–S359 (Abs. 292).
[13] Collinet P, et al., Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J 2006;17:315–20.

disappeared with a follow-up of 2-9 months. 59% of the symptomatic patients required partial or complete excision of the mesh with vaginal closure under general anesthesia. The surgery ranged from 15-40 minutes in duration and was successful 77% of the time. 11% of the patients undergoing a primary repair required a second operation because of recurrence. The incidence of the de novo dyspareunia was 12% with vaginal mesh exposure and 11% in those who had no exposure post operatively.[14]

Sola in a 2006 report describes 42 mesh procedures using Gynemesh PS mesh for both cystocele and rectocele, having no postoperative complications and a 95% success for cystocele and 100% success for rectocele repair.[15]

Hoenil Jo in 2007 evaluated 26 patients with stage III or IV pelvic organ prolapse for 2 years after Gynemesh vaginal repair. Success was 94% objective cure with no tissue erosion or infections noted.[16]

Takeyama described in 2007 a modification of the Prolift procedure using Gynemesh PS. They implanted Gynemesh PS in 245 patients with pelvic organ prolapse and had no serious complications and a low recurrence and exposure rate (0.8 and 1.6%, respectively).[17] Al-Nazer and colleagues reported in 2007 the results of their study of 40 patients undergoing either anterior colporrhaphy or implantation of Prolene Soft mesh. They found both groups had improvement in their prolapse, urinary, and sexual symptoms, but the improvement was more significant in the Prolene Soft group. 95% of the Prolene Soft patients were cured, while 70% of the anterior colporrhaphy patients were cured. They also found that operative morbidity was generally lower in the Prolene Soft group.[18]

Caquant and Cosson in 2008 reported on a study of 684 patients undergoing the TVM procedure using Gynemesh PS performed between 2002-2004. The mesh exposure rate without concurrent hysterectomy was 4.7% and medical management was successful in 42% of cases. The study was limited by short-term follow up.[19] In 2008, Letouzey and colleagues reported the results of their study of 63 women undergoing cystocele repair using Gynemesh PS between 1999-2001. The patients were followed for five years, and the authors observed an 80%

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[14] Deffieux X, et al., Vaginal mesh extrusion after transvaginal repair of cystocele using a prosthetic mesh: Treatment and functional outcomes. J Gynecol Obstet Biol Reprod (Paris) 2006 Nov;35(7):678–84.

[15] Sola V, et al., Tension Free Monofilament Macropore Polypropylene Mesh (Gynemesh PS) in Female Genital Prolapse Repair. Int Braz J Urol 2006;32(4):410–15.

[16] Jo H, et al., Efficacy and outcome of anterior vaginal wall repair using polypropylene mesh (Gynemesh). J Obstet Gynecol Res 2007 Oct;33(5):700–04.

[17] Takeyama M, et al., Feasibility of the Tension-Free Vaginal Mesh Procedure Using Soft Polypropylene Mesh (Gyunemesh PS) in Japan. Int Urogynecol J 2007;18(Supp. 1):S25–S105 (Abs. 079).

[18] Al-Nazer MA, et al., Comparative Study Between Anterior Colporrhaphy Versus Vaginal Wall Repair with Mesh for Management of Anterior Vaginal Wall Prolapse. Int Urogynecol J 2007;18 (Suppl. 1):S25–S105 (Abs. 084).

[19] Caquant F, et al., Safety of Trans Vaginal Mesh procedure: Retrospective study of 684 patients. J Obstet Gynaecol Res 2008 Aug;34(4):449–56.

anatomic cure rate with an additional 20% improved. The vaginal exposure rate was 16% and no patient required reoperation for recurrent prolapse.[20]

In 2009, Natale and colleagues reported the results of an RCT studying Gynemesh PS and Pelvicol with two years of follow-up. They observed a 6.3% erosion rate in the Gynemesh PS patients, and four of the six of those patients underwent a concomitant hysterectomy. The cure rate for the Gynemesh PS cohort was 71.9%. Pre-operative pain was reported by 14 patients in the Gynemesh PS group and that dropped to 0 patients after surgery. Pre-operative dyspareunia was reported by 20 patients in the Gynemesh PS group, and that number dropped to 10 patients after surgery.[21]

Miller and colleagues, in 2011, reported the five-year results of 85 patients undergoing Gynemesh PS anterior and posterior repair with and without hysterectomy. The success rate in the treated compartment at five years was 77%, and the rate of mesh exposure was 19%. Before surgery, 21 patients reported unprovoked vaginal pain, 23 reported pain on examination, 15 had cystalgia, 24 had pain during Valsalva, and 46 had pain with prolonged standing. By five years, only one patient reported pain, which occurred on examination only. At five years, only one case of de novo dyspareunia was observed in those patients who were sexually active before surgery, while resolution of dyspareunia occurred in at least eight of twelve patients with pre-existing dyspareunia. The authors concluded that the TVM procedure remains stable over time when measuring both quality of life and vaginal prolapse symptom scores.[22] Young-Suk Lee and colleagues in 2010 reported on their study of the treatment of 49 women undergoing transvaginal repair of pelvic organ prolapse with Gynemesh PS. They noted a 71.4% cure rate and an improvement rate of 18.4%. They observed only one vaginal erosion at the 12-month follow-up, which was asymptomatic. The authors concluded that "[t]rans-vaginal repair of an anterior vaginal wall prolapse with the monofilament polypropylene mesh Gynemesh™ PS is an effective and safe procedure."[23] Cuevas et al. reported in 2011 on a study involving the use of Gynemesh PS to create a Prolift-like device for treatment of severe pelvic organ prolapse. They observed a low recurrence rate, low rates of intraoperative and perioperative complications, and a low rate of mesh erosion. The study population was 100% satisfied with surgery, and 89.5% found the surgery improved their quality of life.[24]

Farthmann and colleagues studied 200 patients receiving either non-absorbable polypropylene mesh or a partially absorbable polypropylene mesh for cystocele treatment over

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[20] Letouzey V, et al., Long-Term Results after Trans-Vaginal Cystocele Repair Using a Tension-Free Polypropylene Mesh. J Minimally Invasive Gynecol 2008;15:S1–S159 (Abs. 102).
[21] Natale F, et al., A prospective, randomized, controlled study comparing Gynemesh®, a synthetic mesh, and Pelvicol®, a biologic graft, in the surgical treatment of recurrent cystocele. Int Urogynecol J 2009;20:75–81.
[22] Miller D, et al., Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ Prolapse—5 Year Results. Female Pelvic Med & Reconstr Surg 2011 May/Jun;17(3):139–43.
[23] Lee YS, et al., Efficacy and Safety of "Tension-Free" Placement of Gynemesh PS for the Treatment of Anterior Vaginal Wall Prolapse. INJ 2010;14:34–42.
[24] Cuevas R, et al., Prolift Like (PL) Surgery: A Management Option for Severe Pelvic Organ Prolapse (POP) in a Public Hospital in a Developing Country. Int Urogynecol J 2011;22 (Suppl. 2):S197–S1766 (Abs. 1108).

three years. Consideration of mesh weight and foreign material were correlated with 200 patients randomized to conventional or a partially absorbable mesh. Management of mesh exposure, satisfaction with surgery, and postoperative pain were evaluated. Rate of mesh exposure was smaller in the partially absorbable mesh at 3.4% vs 7.5% at 36 months, but the authors found the rate of exposure to be low in both groups. Of the 200 patients, 27 patients had exposure of mesh, with 11 requiring surgical intervention. The rate of recurrent vaginal prolapse was higher in the partially absorbed mesh group. The mesh weight in the nonabsorbable group was 29 g/m^2 with porosity >75 µm. Interestingly, exposure rates varied from 0 to 20.4% between hospital groups, indicating that surgical technique is an important outcome-determining factor. Statistically significant risk factors for exposure uncovered were concomitant hysterectomy, smoking, cesarean section, and a longer incision. The authors concluded that use of synthetic mesh was a safe technique for treatment of pelvic prolapse. Patient satisfaction rates did not vary between the two groups.[25]

Samour and colleagues, in 2014, described the safety and efficacy of using Gynemesh PS for cystocele repair using a minimally invasive technique of transvaginal corkscrew application through the obturator foramen. 152 patients who underwent repair for cystocele grade 2 or greater using Gynemesh PS were followed for up to 36 months with a variable degree of dyspareunia observed in the first 3 months and marked improvement and even disappearance of pain for 90% of patients by the end of 6 months. 3% had persistent dyspareunia by the conclusion of the study. The rate of mesh exposure was 3.3%, reportedly due to the avoidance of excising vaginal epithelium and full-thickness dissection with lack of tension on the mesh. The authors concluded that transobturator placement of Gynemesh PS can be considered a minimally invasive and promising method for correction of cystocele and stress incontinence based on low rate of complications, high rate of success, and low incidence of recurrence.[26]

Dr. Marcus Carey and colleagues, in 2009, reported the results of a randomized controlled trial comparing anterior and posterior vaginal repair with Gynemesh PS augmentation or traditional anterior and posterior colporrhaphy. The success rate in the mesh group at one year post-op was 81%, but only 65% in the traditional anterior and colporrhaphy group. Patients had a high level of satisfaction with the surgery and both groups showed improvements in symptoms and quality-of-life data. New-onset dyspareunia was reported in 16% of sexually active women in the mesh group versus 15% in the non-mesh group.[27]

In 2006, Boulanger and colleagues published the results of a study in which they placed five different meshes—Vicryl, Vypro, Prolene, Prolene Soft, and Mersilene in the peritoneum of pigs to study the tissue integration and tolerance of the meshes. The authors found that the absorbable prostheses made of Vicryl and the non-absorbable prostheses made of polypropylene (i.e., Prolene and Prolene Soft) induced the least severe inflammatory reactions and produced the

[25] Farthmann J, et al., Lower exposure rates of partially absorbable mesh compared to nonabsorbable mesh for cystocele treatment: 3-year follow-up of a prospective randomized trial. Int Urogynecol J 2013;24:749–58.
[26] Samour H, et al., Minimally invasive cystocele repair technique using a polypropylene mesh introduced with the transobturator route. Arch Gynecol Obstet 2015 Jan;291(1):79–84.
[27] Carey M, et al., Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. Br J Obstet Gynecol 2009 Sep;116(10):1380–1386.

best tissue integration. They concluded that Type I Amid monofilament material, such as polypropylene, seemed to be the best integrated and tolerated.[28] Memon developed a biomechanical test to evaluate mesh-reinforced repair as compared to suture-reinforced repair in an animal model. The conclusion of the study was that Gynemesh PS was the least likely synthetic material to fail after repeated cycles of stressing, and was superior to xenograft-reinforced repair and to suture-only repair.[29] In an animal study published in 2007, Bhende and colleagues studied Prolene Soft and other synthetic meshes, as well as naturally derived meshes, to observe the extent to which the meshes served "as a nidus for microbial attachment and growth, thus exacerbating surgical site infection." They found that "[t]he synthetic meshes did not potentiate infection . . . whereas the naturally-derived meshes did."[30]

A 2013 study looked at how pelvic organ prolapse affects sexual function and found that the use of mesh in anterior compartment repair was not associated with a worsening in sexual function or an increase in de novo dyspareunia when compared to traditional anterior colporrhaphy. It also noted that up to 64% of sexually active women attending a urogynecology clinic suffer from female sexual dysfunction.[31] Lowman and colleagues have reported that pelvic organ prolapse repair appears to have a high rate of associated dyspareunia regardless of whether the surgery is performed transvaginally or transabdominally. They also noted that baseline rates of dyspareunia range between 8–43% in women with pelvic organ prolapse, and that this fact makes the evaluation of de novo dyspareunia following prolapse repair quite difficult.[32]

Ongoing technological advances of synthetic meshes using polypropylene have been a moving target, with development of lighter and less stiff materials over the last 10 years. At the time of introduction of Gynemesh PS in the early 2000s, the material was considered the least stiff and most porous mesh to receive FDA clearance and introduction into the surgical market. The stiffness, weight, and porosity of Gynemesh PS has subsequently moved to the middle of the spectrum of synthetic mesh products as recent science has favored the least stiff, lightest weight, and most porous material possible. Nonetheless, Gynemesh PS is still a lightweight, large-pore mesh. There is a point of diminishing returns, as some of the lightest weight meshes have the most deformation and can fail in the physiologic environment of the vagina. Complications that are described are more related to surgical technique and patient selection than the individual mesh product used. The avoidance of large and "T" incisions, concomitant hysterectomy, tobacco use, obesity, exposure to radiation therapy for pelvic cancer, chronic use of steroids, and advanced age all play a significant role in the incidence of vaginal mesh exposure. Injury to either bladder intestine or rectum is a direct result of surgical misadventure. Patients with

[28] Boulanger L, et al., Tissue integration and tolerance to meshes used in gynecologic surgery: An experimental study. Eur J Obstet & Gynecol and Reprod Biol 2006;125:103–08.
[29] Memon HU, et al., Comparison of graft-reinforced repairs and suture repair using a novel biomechanical test
[30] Bhende S, et al., Infection Potentiation Study of Synthetic and Naturally Derived Surgical Mesh in Mice. Surg Infections 2007;8(3):405–14.
[31] Dietz V and Maher C, Pelvic organ prolapse and sexual function. Int Urogynecol J 2013;24:1853–1857.
[32] Lowman JK, et al., Does the Prolift system cause dyspareunia? Am J Obstet Gynecol 2008 Dec;199:707.e1–707.e6.

symptomatic and increasing vaginal prolapse who have failed previous native suture plication often require augmented repairs with xenograft or synthetic materials.

The Prolift device was the most studied mesh kit for pelvic organ prolapse treatment and the studies showed high success rates with minimal complications.[33] Van Raalte in 2007 studied 350 patients undergoing the Prolift procedure with median follow-up of 6 months, and observed a mesh exposure rate of 1.1%, with all treated with office resection and/or vaginal estrogen. The postoperative pop-Q cure rate was 90.6% with a dyspareunia rate of 6.3%. One patient required in office vaginal injection for pain treatment and 1 patient had a surgical mesh resection.[34]

Withagen and colleagues, in 2011, published the results of a randomized controlled trial comparing 97 women undergoing conventional repair and 93 women undergoing Prolift repair. One year after surgery, they found anatomic failure of the procedure in 45.2% of the patients undergoing a conventional repair and in 9.6% of the Prolift patients ($p < .001$; OR 7.7; 95% CI 3.3-18). Fourteen of the Prolift patients (16.9%) had a mesh exposure, but nine of the fourteen were asymptomatic and treated with local estrogen only. Five underwent an additional outpatient surgery to excise the exposed mesh. Those exposures resolved. In both groups, dyspareunia decreased at twelve months compared to baseline, and there was no statistically significant difference between the two groups. There was no statistically significant difference in de novo dyspareunia between the two groups at twelve months.[35]

In 2011, Altman and colleagues published in the New England Journal of Medicine their multi-center RCT comparing anterior colporrhaphy and Prolift surgery for the treatment of cystocele. They found that the primary endpoint of success (POP-Q stage 0 or 1) was significantly more common in the Prolift group (60.8%) than it was in the colporrhaphy group (34.5%). The rate of intra-operative hemorrhage was higher in the Prolift group. Re-operation to correct mesh exposure during the one-year follow-up period occurred in only 3.2% of the 186 patients in the Prolift group. Dyspareunia was higher in the Prolift group, but the difference was

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[33] Halaska M, et al., A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol 2012;207:301.e1–7; da Silveira S, et al., Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. Int Urogynecol J 2015 Mar;26(3):335–342; Svabik K, et al., Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol 2014 Apr;43(4):365–371; de Landsheere L, et al., Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol 2012 Jan;206(1):83.e1–7; Withagen MI, et al., Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2011 Feb;117(2):242–250; Sokol AI, et al., One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. Am J Obstet Gynecol 2012 Jan;86:e1–e9; Altman D, et al., Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse. N Engl J Med 2011;364:1826–1836.

[34] van Raalte H, et al., Short-Term Results of the Prolift Procedure in 350 Patients Used in the Treatment of Pelvic Organ Prolapse. Int Urogynecol J 2007;18 (Suppl. 1):S25–S105 (Abs. 083).

[35] Withagen MI, et al., Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse. Obstet Gynecol 2011 Feb;117(2 Pt 1):242–50.

not statistically significant. There was no statistically significant difference in pelvic or genital pain between the two groups.[36]

Halaska and colleagues published the results of their randomized controlled trial involving 168 patients receiving either a Prolift or SSLF with one-year follow-up. Prolapse recurred after 12 months in 39.4% of the SSLF patients and 16.9% of the Prolift patients ($p = 0.003$). Mesh exposures occurred in 20.8% of the Prolift patients, but only 25% of those were symptomatic. Six of the symptomatic erosions resolved with local estrogen therapy and ten were surgically treated—six under general anesthesia and four under local anesthesia, but all successfully treated. Overall, only 7.6% of all the mesh patients required resection under general anesthesia.[37]

Sokol and colleagues in 2012 reported on the results of their one-year randomized controlled trial comparing treatment of women with women with stage ≥ 2 prolapse with either traditional repair or Prolift. They found that both operations resulted in objective and subjective improvement of prolapse, but the mesh resulted in a higher reoperation rate. They saw a 15.6% mesh exposure rate and a 9.3% reoperation rate for exposure in the Prolift group. All of the exposures resolved after outpatient trimming without further exposures. In the traditional repair patients, 15% had apical Gore-Tex suture exposures. Despite the 15.5% exposure rate in the Prolift patients, both groups had high subjective satisfaction at one year, and there was no significant difference found between the groups with respect to sexual function at one year.[38]

In 2014, Svabik and colleagues published a study comparing Prolift surgery to sacrospinous ligament fixation surgery in patients who had had a hysterectomy and a levator ani avulsion injury. At one-year follow-up, they saw a 3% rate of anatomical failure in the patients who received Prolift repair, and a 65% frate of anatomical failure in the SSLF group. There were no major complications such as heavy bleeding, bladder injury, or bowel injury in either group. There were three mesh exposures in the Prolift group at the three-month follow-up but no additional exposures at the one-year follow-up. One of those three was asymptomatic and treated conservatively. Re-operation for stress urinary incontinence was significantly higher in the Prolift group, but the authors theorized that the lower rate in the SSLF group may have resulted from a higher incidence of urethral king in the SSLF group, which masked stress incontinence in those with recurrent cystocele. Dyspareunia rates were low, with two patients experiencing it in the Prolift group and one in the SSLF group.[39]

In 2015, da Silveira and colleagues published the results of their multi-center randomized trial comparing native tissue repairs with Prolift. The authors found that complications were

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[36] Altman D, et al., Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse. N Engl J Med 2011 May;364(19);1826–36.

[37] Halaska M, et al., A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol 2012 Oct;207:301.e1–7.

[38] Sokol AI, et al., One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. Am J Obstet Gynecol 2012 Jan;206:86.e1–9.

[39] Svabik K, et al., Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol 2014 Apr;43(4):365–71.

statistically significantly higher in the mesh group, but the "only between-group difference was related to mesh exposure, which occurred in 20% of the patients in the mesh group. Of those patients, however, only three patients required revisions surgery; in the other fifteen patients the exposure was treated with topical estrogen. The numbers of patients with dyspareunia, pain, and recurrence of prolapse were higher in the native tissue cohort, but the differences were not statistically significant. Quality of life scores were significantly improved in each group, but there was a greater improvement of quality of life in the mesh group despite the increased rate of exposures. Anatomical efficacy was higher in the mesh group in the anterior compartment.[40]

Benbouzid and colleagues did a study of Prolift patients with 4.5-year follow-up. They observed an 85.3% cure rate (defined as POP-Q stage 0–1) with no recurrence. Mesh exposure only occurred in 4 of the 75 patients (5.3%); two of whom were treated with topical estrogen, and two who underwent revision. There were no recurrences beyond POP-Q Stage II.[41]

De Landsheere and colleagues conducted a retrospective single-center study of 524 patients undergoing Prolift, with a median follow-up of three years. The global reoperation rate was 11.6%. They found the rate of mesh complications was low.[42]

Maher and colleagues more recently analyzed 37 randomized controlled trials involving 4,023 women comparing different types of vaginal repair (mesh, biologic graft, or native tissue) and their analysis was recently published by The Cochrane Collaboration. While they found more women in the mesh group needed reoperation for the combined outcome of prolapse, SUI, or mesh exposure, rates of repeat surgery for prolapse were lower in the mesh group, and there was no evidence of a difference between the mesh and other groups in rates of repeat incontinence surgery. Eight percent of the mesh patients needed reoperation for mesh exposure. Recurrent prolapse was less likely in the mesh patients than in the other patients. The authors found no evidence of a difference in dyspareunia rates between the groups, and the mesh patients awareness of prolapse at 1–3 years was less likely than for the patients in the other groups.[43]

I have personally performed over 1,000 procedures involving implantation of Prolene polypropylene mesh for treatment of stress urinary incontinence or pelvic organ prolapse, and have found the Prolene polypropylene products to be safe and efficacious when following the appropriate patient selection and the technique described by the product instructions for use and sound medical judgment and surgical technique and concepts. I have lectured and proctored physicians on the safe use of Prolene polypropylene devices for pelvic floor surgery since 2000. The devices are high quality, straightforward, and the polypropylene mesh is stable over time, as I have patients implanted 15 years ago and see no long-term complication trends. Since the television advertisements claiming pelvic mesh is a dangerous product, I have received hundreds

[40] Da Silveira, et al., Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. Int Urogynecol J 2015 Mar;26(3):335-42.
[41] Benbouzid S, et al., Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after a 4.5 years follow up. Int J Urol 2012;19:1010–1016.
[42] de Landsheere L, et al., Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol 2012 Jan;206(1):83.e1–7.
[43] Maher C, et al., Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev. 2016 Feb 9;2:CD012079.

of phone calls from anxious patients with fears of product recalls and future complications. The overwhelming majority of those anxious patients have excellent outcomes and no adverse symptoms. The effect on current patients is to create fear that a synthetic sling will cause future problems and many choose not to proceed to treatment. There is a 30% reduction in the number of patients undergoing stress incontinence and pelvic reconstructive surgery.[44]

As set forth above, the efficacy and safety of the Ethicon's Gynemesh PS and Prolift is well-reported. The peer-reviewed, published clinical data shows that procedures involving Gynemesh PS and the Prolift device can be performed safely and effectively. The studies show that most patients do not experience dyspareunia or pelvic pain after undergoing transvaginal mesh repair for pelvic organ prolapse.

Additionally, the professional organizations AUGS and SUFU—non-profit organizations representing over 2,000 practicing physicians, nurse practitioners, physical therapists, nurses, health care professionals and researchers dedicated to treating female pelvic floor disorders—have made the following statements regarding the safe use of polypropylene and the benefits of providing surgeons with options for treating pelvic floor disorders:

Polypropylene material is safe and effective as a surgical implant. Polypropylene has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years.[45]

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> The American Urogynecologic Society strongly opposes any restrictions by state or local medical organizations, healthcare systems, or insurance companies which ban currently available surgical options performed by qualified and credentialed surgeons on appropriately informed patients with pelvic floor disorders.[46]

I agree with these position statements.

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[44] Perkins CE, Warrior K, Eilber KS, et al. The Role of Mid-urethral Slings in 2014: Analysis of the Impact of Litigation on Practice. Curr Bladder Dysfunct Rep (2015) 10:39-45. DOI 10.1007/s11884-014-0278-z; Koo K, Gormley EA, Abstract MP81-05: Transvaginal Mesh in the Media Following the 2011 FDA Update.

[45] AUGS-SUFU, Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 3, 2014).

[46] AUGS Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders (2013).

Plaintiffs' experts' theory of mesh degradation is not substantiated in the literature or in my personal experience using polypropylene slings and mesh for incontinence treatment and pelvic reconstruction. Studies of explanted mesh are difficult to interpret, as there is damage to the material during explantation, treatment with chemicals to remove the collagen and biologic matrix that has incorporated into the mesh, and preparation onto slides for microscopic examination. There is no literature to support clinically significant mesh degradation in humans. Polypropylene suture is used by vascular surgeons on major blood vessels and in my practice when tying off renal arteries and repairing the largest vein in the body; the vena cava. If there was a question of degradation or loss of strength over time, Prolene suture would not be the suture of choice for the highest-risk surgery. The studies often relied on by plaintiffs' experts offering the opinion that the Prolene mesh degrades are unreliable and do not support that theory. For instance, the Clavé study from 2010 is unreliable and does not show degradation. The chemical analyses performed on a limited subset of the specimens does not show degradation, and the scanning electron microscope photos in the study show surface cracking that could be from biologic material and handling or preservation rather than the cracking of the polypropylene itself. Also, the sample analyzed in the study was only 32 out of the 100 specimens, and the authors fail to discuss how those 32 specimens were selected. They also fail to discuss whether the mesh was damaged during surgical explantation.

Nor have I seen a problem with shrinking, contraction or pore collapse when placed according to the IFU. Scar tissue that forms after any pelvic surgery contracts, and tissue incorporating into implanted mesh is no exception, but the mesh itself does not contract.

Some plaintiffs' experts' have said that placement of transvaginal mesh is dangerous and violates one of the most basic tenets of surgical teachings in that it involves placing a permanent implant into a human through a contaminated surgical field . If that theory was correct, the majority of patients receiving transvaginal mesh would have infections. However, vaginal infections following implantation of transvaginal mesh are very rare. Such opinions by plaintiffs' experts are not borne out in facts. There are tens of thousands of women with transvaginally placed mesh who are doing well, including in my own practice in the past fifteen years. If what plaintiffs' experts are saying was true, the majority of patients would have complications rather than a small percentage. Operative prep of the vagina is performed prior to the surgery, which maximizes sterility. The available medical literature does not indicate an increased risk of infection with transvaginal mesh procedures like the Prolift.

Plaintiffs' experts contend that the Prolift is defective and/or dangerous because it involves "blind" passage of the graft. However, many pelvic floor surgical procedures are performed with tactile palpation based on a knowledge of relevant anatomy, and the Prolift is no different in that regard. Injury to adjacent organs and vessels is a risk of all prolapse surgeries, not just those involving mesh grafts placed transvaginally.

There is no practical or clinical difference between mechanically cut or laser-cut mesh in terms of how it is deployed or incorporated in the tissues.[47] Mesh is not pre-stretched to 50%

[47] ETH.MESH.01784823-28 (CER Laser Cut Mesh); ETH.MESH.01222075-79 (Elongation Characteristics of Laser Cut Prolene Mesh for TVT); ETH.MESH.06696367-79 (Performance Evaluation

elongation before it is used. The mesh must have porosity large enough to encourage fibroblast and collagen deposition for incorporation, and it must have enough elasticity to allow give during dynamic stressing that occurs with activity. Mesh requires an optimal level of stiffness to properly do its job. Both laser-cut and mechanically cut Prolene mesh is safe and efficacious as demonstrated by the medical literature and in my experience.

Plaintiffs' experts have also claimed that the Gynemesh PS mesh in the Prolift is cytotoxic and causes an excessive inflammatory response. This is not supported in the literature, and I have not seen it in my practice. The mere presence of chronic inflammatory cells in a tissue specimen does not prove that there is a chronic inflammatory process that is active. Such cells can be present but quiescent, and can be seen in vaginal tissue even when no mesh or other foreign body has been implanted.

Plaintiffs' experts may claim that Ultrapro or Vypro mesh would have been a safer alternative to the Prolene Soft mesh. However, with respect to Vypro, a study of the use of that mesh in pelvic floor surgery showed that tolerance of the Vypro mesh was "very poor" and associated with high rates of erosion and cicatrisation.[48] With respect to Ultrapro, the study often cited by plaintiffs' experts in support of that material as a safer alternative to the Prolene TVT mesh is the Okulu study, but that study shows the same number of erosions (2) occurred in both the Prolene Soft cohort and the Vypro cohort, despite Vypro's larger pore size and lighter weight, and that the Ultrapro group just had one fewer erosion.[49]

Plaintiffs' experts sometimes suggest or claim that mesh made of Prolene polypropylene is carcinogenic, but there is no reliable scientific evidence to support the theory or claim that polypropylene can cause cancer or sarcoma. In the more than 1,000 cases in which I have implanted one of the Ethicon Prolene polypropylene products, I have not seen a single case of cancer attributable to the mesh. The literature also refutes plaintiffs' experts' suggestion or claim.[50] (King AB, et al. Is there an association between polypropylene midurethral slings and malignancy? Urology. 2014 Oct;84(4):789-92; King AB, Goldman HB. Current controversies regarding oncologic risk associated with polypropylene midurethral slings. Curr Urol Rep. 2014 Nov;15(11):453; Linder BJ, et al., Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J 2016 DOI:10.1007/s00192-016-2961-4.) The medical literature contains no case reports of tumors caused by or associated with polypropylene implantation despite the fact that polypropylene has been implanted in

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of TVT U Prolene Mesh); Lin AT, et al., In Vivo tension Sustained by Fascial Sling in Pubovaginal Sling Surgery for Female Stress Urinary Incontinence, J Urol , 2005 Mar;173(3):894–897.

[48] Denis S, et al., Pelvic Organ Prolapse Treatment by the Vaginal Route Using a Vypro Composite Mesh: Preliminary Results About 106 Cases. ICS IUGA 2004; Abstract 620.

[49] Okulu E, et al., Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications. Sand J Urol 2013;47:217–224.

[50] King AB, et al. Is there an association between polypropylene midurethral slings and malignancy? Urology. 2014 Oct;84(4):789-92; Moalli P, et al., Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J 2014, DOI 10.1007/s00192-014-2343-8; King AB, Goldman HB. Current controversies regarding oncologic risk associated with polypropylene midurethral slings. Curr Urol Rep. 2014 Nov;15(11):453.

millions of people. (AUGS & SUFU, Frequently Asked Questions by Providers—Mid-urethral Slings for Stress Urinary Incontinence (available at http://www.augs.org/p/bl/et/blogaid=194).)

V. Prolift's Instructions for Use and Other Educational Materials

a. Ethicon's Instructions for Use, Surgical Technique Guide, and Surgeon's Resource Monograph

Each Prolift device was accompanied by an Instructions for Use (IFU) document. The IFU describes the Prolift Total, Anterior, and Posterior Pelvic Floor Repair Systems. It notes that the systems "are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect." (ETH.MESH.02341522-89.) It contains a detailed description of the total, anterior, and posterior implants, and diagrams that demonstrate the general use of each device. The IFU starts with a request to the user to "Please read all information carefully," and then cautions that "[f]ailure to properly follow instructions may result in improper functioning of the devices and lead to injury." It also notes that "[t]raining on the use of the GYNECARE PROLIFT Pelvic Floor Repair Systems is recommended and available," and advises the user to contact his or her company sales representative to arrange for the training. The IFU also directs the surgeon to "[r]efer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair Systems for further information on the GYNECARE PROLIFT procedures." It also provides instructions for the placement of sutures, staples, or other fixation devices (if used) at a certain distance away from the edge of the mesh The IFU sets forth the contraindications for using the product.

The IFU then sets forth Warnings and Precautions and potential Adverse Reactions. It cautions that "[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems." It also notes that "[a]cceptable surgical practices should be followed in the presence of infected or contaminated wounds," and advises that after surgery, patients "should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities." The IFU warns the surgeon to "[a]void placing excessive tension on the mesh implant during handling." It also directs the surgeon to "[r]efer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures." The IFU warns the surgeon to use the Prolift "with care to avoid damage to vessels, nerves, bladder and bowel," and that "[a]ttention to patient anatomy and correct use of the device will minimize risks." It warns that "[t]ransient leg pain may occur and advises that it can usually be managed with mild analgesics. It also notes that the potential adverse reactions associated with the device "are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction." Finally, it warns that "[p]unctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

The IFU and the warnings contained therein are adequate and allow for the safe use of the device. The instructions are such that a trained and experienced physician could implant the mesh safely and effectively. The IFU is not intended to teach surgical technique, which is assumed to have been in the skill set of the surgeon. Every surgeon should be aware of the intraoperative and post-operative risks inherent in the use of surgical mesh. A surgeon need not be taught the entire practice of medicine in an IFU. The totality of surgical risks is not included in the IFU for surgeons. Surgeons have training from numerous sources—medical school, residency, maybe fellowships, colleagues' experiences, their own experience, literature, etc. The IFU is used by the surgeon to become familiar with the specific device, the handling, placement and deployment in the manner that maximizes safety and efficacy. The IFU is never assumed to be a completely comprehensive list of all the possible adverse complications that are low prevalence. The IFU is intended to guide the surgeon to perform the procedure as the device was designed.

Mesh exposure and erosion or extrusion are the only unique risks to mesh surgeries, and are essentially wound complications. Wound complications can also occur with other surgeries. Mesh exposure can be caused by poor quality tissue due to atrophic vaginitis, history of pelvic radiation therapy, too superficial dissection prior to sling placement, hematoma, tobacco usage, and early sexual activity.

The IFU lists indications for use, contraindications, most prevalent risks, and a detailed description of how to deploy the mesh safely. IFUs in general are not intended to list every possible adverse event or post-operative complication. The IFU is generally understood to be a guide in the proper deployment of the device. Surgeons are trained in residency how to manage vaginal surgery with anatomy, handling of tissues, defining surgical planes, and perioperative care. The IFU functions to describe how this particular device is best deployed but the patient selection, preoperative informed consent, perioperative management, and post-operative care of the patient is the surgeon's responsibility. The patient's degree of severity of vaginal prolapse, with consideration of patient age, tissue integrity, previous pelvic surgery, health status, tobacco usage, and steroid or opioid dependency leads the surgeon to make a complex decision about surgical approach and the likelihood of success.

Plaintiffs' experts may claim that pain, dyspareunia should have been warned about in the IFU. I disagree. Pelvic floor surgeons know that pain and dyspareunia may occur with any pelvic floor surgery, and they know that any surgical complications can be temporary or permanent. Surgeons know that surgical complications can be mild, moderate, or severe. Surgeons need not be specifically warned in an IFU of these fundamental surgical risks. Published data supports the fact that dyspareunia rates following pelvic floor surgery with Prolene Soft mesh are low.[51]

[51] Fatton B, et al., Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift™ technique)—a case series multicentric study. Int Urogynecol J 2007;18:743–752 (noting that among the 30 patients known to be sexually active, 76.6% had resumed sexual intercourse at three months follow-up, while only three patients complained of dyspareunia); Paplomata E, et al., Genital Floor Repair Using Polypropylene Meshes: a Comparative Study. 2007 (Abs. 482) (noting that only two patients of 56 that underwent prolapse repair with Gynemesh or Prolift developed dyspareunia during 21-month follow-up); Jacquetin B, et al., Total transvaginal mesh (TVM) technique for treatment

Ethicon also produced a Surgical Technique Guide and a Surgeon's Resource Monograph. The Surgical Technique Guide provided detailed instructions on preparing the patient for Prolift surgery and the total, anterior, and posterior procedures performed in conjunction with vaginal hysterectomy. It noted that "[r]etrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TVM procedure with and without concurrent hysterectomy, or where the patient had a prior hysterectomy (for the Prolift Total procedure)." The Surgeon's Resource Monograph was based in part on the experience of pelvic floor surgeons from around the world who had performed Prolift procedures in a large number of cases. The Monograph provided background information on the development of Prolift, and correctly noted that it contained "information that is not available on most procedures." It set forth expert opinions on the use of the Prolift Total, Anterior, and Posterior Pelvic Floor Repair System, and discussed patient selection and preparation, surgical technique, anesthesia and hydrodissection, incisions, additional sutures, mesh handling, and complications including hemorrhage, visceral injury, infection, erosion, exposure, extrusion, dyspareunia and vaginal pain. It also included a summary of the available clinical data. The instructions and warnings provided by Ethicon in these documents were adequate and helpful to surgeons.

Ethicon also provided a professional education program that supplemented the IFU. There was a preceptorship in which physicians would attend didactic lectures discussing patient selection, surgical technique, and literature on the device, followed by time in a cadaver lab spent learning how to implant the devices. Surgeons were also provided the opportunity to observe other surgeons implanting the devices in patients, or to have a surgeon experienced in using the device scrub in on a surgery to oversee the surgeon's implantation of the device. Complications and the management of complications were discussed in these professional education programs, which were extremely helpful. This professional education program did not, however, take the place of surgeon credentialing at the hospital level.

c. Prolift Brochures

Ethicon produced brochures regarding the Prolift device, which surgeons could provide to patients considering surgical treatment of their pelvic organ prolapse. The brochures background information regarding pelvic organ prolapse such as a general description of pelvic organ prolapse, the various symptoms one can experience with pelvic organ prolapse, the causes of the condition, and how common it is. The brochures also described the various types of pelvic organ prolapse and provided diagrams depicting the various types. The brochures discussed treatment options—both conservative and surgical—for pelvic organ prolapse, and noted that patients "should undergo a thorough evaluation to ensure a proper diagnosis" of pelvic organ prolapse. (ETH.MESH.03904968–75.) They described the Prolift device, how it is different from other surgical alternatives, and how the device works. They provide information on what the patient can expect during the procedure and after they go home, and they discussed risks of the Prolift procedure, including "injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury," and exposure of the mesh into the vaginal canal. All of this information was set forth in terms that are understandable to those without any medical

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of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J 2013 Oct;24(10):1679–1686.

training. The brochures then set forth the indications, contraindications, warnings and precautions, and adverse reactions associated with the device.

The product brochures provided adequate information regarding the Prolift device and was helpful to patients in my practice. The brochures did not, however, serve as a substitute for a comprehensive informed consent discussion between the surgeon and the patient.

VI. The Design of Prolift

a. The Usefulness, Desirability, and Safety of the Prolift Device

Gynemesh PS mesh—the mesh used in the Prolift device—is very useful to surgeons because it is a lightweight, large-pore, knitted, monofilament Prolene polypropylene mesh that is well-tolerated by the body and adds needed reinforcement to native tissue for repair of fascial defects. The large pore-size of the mesh allows for tissue incorporation and the passage of macrophages and leukocytes to help clear any bacteria that could lead to an infection. Unlike allograft or xenograft material, synthetic mesh like Gynemesh PS is readily available, is not met with cultural or religious objections, and presents no risk of disease transmission by viruses, prions, and bacteria.

The polypropylene monofilament used to knit the mesh has been safely used in surgery as suture throughout the body for over 50 years, and has been shown to be stable and does not degrade in the body over time. The device is also useful because it comes with instructions for use, a tracking lot number for safety and batch analysis, as well as MDR reporting and FDA analyses. The mesh used in the device is not met with cultural or religious objections like allografts or xenografts, and is extremely effective and durable, with very low recurrence rates. As discussed in the studies above, there is an extensive body of literature supporting the safety of the mesh and the efficacy of treating pelvic organ prolapse with the device.

It is comforting as a surgeon to be using a product that is known to have the largest amount of peer-reviewed data from multiple institutions substantiating a safe, reliable, reproducible technique and material. Prolene has been around for 50 years, been safely used in various applications, and the body's reaction to the material is known.

Complications are usually surgery-related and not mesh-specific. Exposures are uncommon and manageable, occurring in a small minority of cases. The cause can be poor tissue integrity caused by estrogen deficiency, delayed wound healing due to diabetes, steroid usage, hematoma formation, or placing the sling too superficially. Treatment includes application of topical estrogen cream, re-closure of the mucosal edges, and limited mesh excision if necessary. The excision can be performed in an office setting under local anesthesia or under light sedation in an OR. Dyspareunia is rare following implantation of the device, and most sexual dysfunction occurring after pelvic organ prolapse surgery is connected to concomitant hysterectomy and/or oophorectomy. Graft-related complications can occur with any material used for augmentation, whether it is synthetic or biologic graft material or synthetic suture material. Abed and

colleagues' systematic review in 2011 showed that erosions happen in 10.1% of patients receiving biological grafts and in 10.3% of patients receiving synthetic grafts.[52]

The trocars used with the Prolift device made it easier to affix the vagina to deep structures that can be difficult to access without such tools. The fact that the mesh was pre-cut for an anterior, posterior, or total repair was also helpful and useful. The device allowed the surgeon to reinforce a prolapse repair with a durable mesh graft in a minimally invasive surgery .

All surgical procedures have inherent risks. All pelvic surgeries have similar risks, and the introduction of the Gynemesh PS mesh and the Prolift device has served to decrease complications when compared to previous techniques. Because native repairs do not involve a kit product, complications are not reportable to the MAUDE database. Scientific research has provided improved materials and applications to both improve efficacy and decrease complications. Synthetic mesh that is microporous or too macroporous has proven to be either less safe or less efficacious. If the mesh is too lightweight or too large pore, there is inadequate support.

All pelvic surgery has similar and inherent risks. Pelvic floor surgeons should be and are aware of the potential complications involved with any surgical treatment of pelvic organ prolapse based on a combination of their medical school education, their residencies, fellowships, their experience, their continuing education, and their review of the device's IFU if a surgical mesh device is used. Risks such as infection, scarring, inflammation, bladder damage, bowel damage, ureter damage, nerve damage, injury to vessels, wound complications (such as wound dehiscence, herniation, hematoma, seroma, pelvic abscess, exposure, and erosion), pain, pelvic pain, groin pain, dyspareunia, fistula, anesthetic risks, bowel or bladder dysfunction, failure of the operation, bleeding, death, pulmonary embolism, myocardial infarction, pneumonia, deep vein thrombosis, and need for reoperation are basic elemental surgical risks of any pelvic floor surgery involving mesh. Surgeons understand that these complications can happen, and they also understand that the symptoms can range in terms of severity and duration.

Surgeons are expected to understand the anatomy in which they are operating, and should identify and dissect in safe planes, avoiding inadvertent damage to the organs and vessels contained within the pelvis. The education and training of the pelvic surgeon should be adequate to know the possibility of complications and their avoidance, risks of recurrence and reoperation. Indeed, the development of biologic and synthetic materials was motivated by the high failure rate of pelvic reconstruction due to the weakness of the patients' connective tissue leading to the condition requiring repair. There is an extensive body of medical knowledge in the medical literature discussing the possibility of complications with the use of meshes. Surgeons' prior experience with mesh informs their understanding of potential complications with pelvic floor surgeries, including those involved with mesh devices. While mesh exposure is unique to mesh devices, it is obvious, and it is general knowledge within female urology and urogynecology. The potential injury to vessels and organs caused by trocars is well-known to surgeons, and potential mesh exposure and foreign body reactions are common knowledge.

[52] Abed H, et al., Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J 2011 Jul;22(7):789–798.

Furthermore, the FDA issued a Public Health Notification in 2008 regarding the use of synthetic mesh for treatment of prolapse and incontinence. It alerted healthcare practitioners to "complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI)." It noted that the major complications were rare, but could have serious consequences, and that the "most frequent complications included erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." It also noted that there were "reports of bowel, bladder, and blood vessel perforation during insertion," and that "[i]n some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia." This Public Health Notification was yet another source of knowledge for surgeons regarding potential complications associated with synthetic mesh midurethral slings, complementing the Prolift's IFU, Ethicon's professional education seminars, and the surgeons' training, education, and experience.

Based upon the analysis above, and on my education, my training, my experience using these products and alternative incontinence treatments, and my reading of the literature referenced above, I believe that Ethicon's Prolift device is not defective, but was reasonably safe for its intended use and had a positive benefit-to-risk profile. It provided better anatomic support than native tissue repairs, and most patients were very satisfied with the Prolift procedure. Recovery times and operative times were minimal, success rates were high, and complication rates were low with the Prolift device. In my opinion, the benefits of the Prolift device outweighed the risks of using the product. At the time the product was launched, I do not believe it could have been made safer for its intended use. The product was state of the art at the time it was launched.

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